

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Kanamycin Acid Sulfate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10/25/2023
2.1	12/15/2023	11272802-00004	Date of first issue: 09/18/2023

SECTION 1. IDENTIFICATION

Product name : Kanamycin Acid Sulfate Formulation
Other means of identification : No data available

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

Specific target organ toxicity : Category 1 (Auditory system)
- repeated exposure (Oral)

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H372 Causes damage to organs (Auditory system) through prolonged or repeated exposure if swallowed.

Precautionary Statements :
Prevention:
P260 Do not breathe mist or vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

Response:
P314 Get medical attention if you feel unwell.

Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards

None known.

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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Kanamycin acid sulfate	No data available	64013-70-3	22.4
Phenol	Monohydroxybenzene	108-95-2	0.235

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.
Get medical attention if symptoms occur.

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Causes damage to organs through prolonged or repeated exposure if swallowed.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do

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Special protective equipment for fire-fighters : so.
Evacuate area.
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g., by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe mist or vapors.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

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Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Kanamycin acid sulfate	64013-70-3	TWA	100 µg/m ³ (OEB 2)	Internal
Phenol	108-95-2	TWA	5 ppm 19 mg/m ³	CA AB OEL
		TWA	5 ppm	CA BC OEL
		TWAEV	5 ppm 19 mg/m ³	CA QC OEL
		TWA	5 ppm	ACGIH

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
Phenol	108-95-2	Phenol	Urine	End of shift (As soon as possible after exposure ceases)	250 mg/g creatinine	ACGIH BEI

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Laboratory operations do not require special containment.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection :
Material : Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a

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potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.

When using do not eat, drink or smoke.

Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : colorless

Odor : characteristic

Odor Threshold : No data available

pH : 3.5 - 5.5

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : 1.05 - 1.10 g/cm³

Solubility(ies)

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Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: > 5 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: > 2,000 mg/kg

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Method: Calculation method

Components:

Kanamycin acid sulfate:

Acute oral toxicity : LD50 (Rat): > 4,000 mg/kg
LD50 (Mouse): 12,000 mg/kg
LD50 (Rabbit): > 3,000 mg/kg

Phenol:

Acute oral toxicity : LD50 (Rat): 650 mg/kg
Method: OECD Test Guideline 401
Acute toxicity estimate (Humans): 140 - 290 mg/kg
Method: Expert judgment

Acute inhalation toxicity : LC0 (Rat): 0.9 mg/l
Exposure time: 8 h
Test atmosphere: dust/mist
Assessment: Corrosive to the respiratory tract.
Acute toxicity estimate (Humans): > 0.9 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Expert judgment

Acute dermal toxicity : LD50 (Rabbit): 660 mg/kg
Method: OECD Test Guideline 402
Acute toxicity estimate (Humans): 300 mg/kg
Method: Expert judgment

Skin corrosion/irritation

Not classified based on available information.

Components:

Kanamycin acid sulfate:

Remarks : No data available

Phenol:

Species : Rabbit
Result : Corrosive after 3 minutes to 1 hour of exposure

Serious eye damage/eye irritation

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Components:

Kanamycin acid sulfate:

Remarks : No data available

Phenol:

Species : Rabbit
Result : Irreversible effects on the eye
Method : OECD Test Guideline 405

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Kanamycin acid sulfate:

Test Type : Maximization Test
Species : Guinea pig
Assessment : Did not cause sensitization on laboratory animals.
Result : negative

Phenol:

Test Type : Buehler Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Kanamycin acid sulfate:

Genotoxicity in vitro : Test Type: Ames test
Result: negative

Test Type: mitotic recombination assay
Test system: Escherichia coli
Result: negative

Test Type: DNA Repair
Test system: Escherichia coli
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse

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Cell type: Bone marrow
Result: negative

Phenol:

- Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: positive
- Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: positive
Remarks: Annex VI From 1272/2008
- Germ cell mutagenicity - Assessment : Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

Carcinogenicity

Not classified based on available information.

Components:

Phenol:

- Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks
Method : OECD Test Guideline 451
Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

Kanamycin acid sulfate:

- Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Intravenous injection
Developmental Toxicity: 100 mg/kg body weight
Symptoms: No adverse effects.
- Test Type: reproductive and developmental toxicity study
Application Route: Intravenous injection
Developmental Toxicity: NOAEL: 400 mg/kg body weight
Symptoms: No adverse effects.
Target Organs: Auditory system
Result: Post-natal toxicity
- Test Type: Reproduction/Developmental toxicity screening test
Species: Guinea pig

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Application Route: Intramuscular
Developmental Toxicity: NOAEL: > 100 mg/kg body weight
Target Organs: Auditory system
Remarks: Significant toxicity observed in testing

Phenol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative

Effects on fetal development : Test Type: Embryo-fetal development
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Causes damage to organs (Auditory system) through prolonged or repeated exposure if swallowed.

Components:

Kanamycin acid sulfate:

Routes of exposure : Oral
Target Organs : Auditory system
Assessment : Causes damage to organs through prolonged or repeated exposure.

Phenol:

Target Organs : Central nervous system, Kidney, Liver, Skin
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Kanamycin acid sulfate:

Species : Rat
LOAEL : TDLo = 12000 mg/kg
Application Route : Intraperitoneal
Exposure time : 30 d
Target Organs : Kidney, Ureter, Bladder
Remarks : Significant toxicity observed in testing

Species : Dog
LOAEL : TDLo= 6500 mg/kg

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Application Route : Subcutaneous
Exposure time : 17 d
Target Organs : Auditory system, Eye, Kidney, olfactory sense organs
Remarks : Significant toxicity observed in testing

Species : Guinea pig
NOAEL : 100 mg/kg
LOAEL : > 200 mg/kg
Application Route : Intramuscular
Exposure time : 4 Weeks
Target Organs : Auditory system
Remarks : Significant toxicity observed in testing

Species : Rabbit, male
LOAEL : > 50 mg/kg
Application Route : Intramuscular
Exposure time : 30 d
Target Organs : Auditory system, Kidney
Remarks : Significant toxicity observed in testing

Phenol:

Species : Rat
LOAEL : 300 mg/kg
Application Route : Ingestion
Exposure time : 90 Days
Method : OECD Test Guideline 408

Species : Rat
NOAEL : ≥ 0.1 mg/l
Application Route : inhalation (vapor)
Exposure time : 74 Days

Species : Rabbit
LOAEL : 260 mg/kg
Application Route : Skin contact
Exposure time : 18 Days

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Kanamycin acid sulfate:

General Information : Target Organs: Auditory system
Symptoms: Abdominal pain, altered taste, Dizziness
Remarks: The most common side effects are:
Target Organs: Kidney
Symptoms: Vomiting, skin rash, numbness

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SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Kanamycin acid sulfate:

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 0.74 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 0.31 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
- EC50 (blue-green algae): 0.03 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
- NOEC (blue-green algae): 0.01 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
- Toxicity to microorganisms : EC50: > 461 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
- NOEC: 4.9 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Ecotoxicology Assessment

- Acute aquatic toxicity : Very toxic to aquatic organisms.
- Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.

Phenol:

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 24.9 mg/l
Exposure time: 96 h

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Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 3.1 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Selenastrum capricornutum (green algae)): 61.1 mg/l
Exposure time: 96 h

Toxicity to fish (Chronic toxicity) : NOEC: 0.077 mg/l
Exposure time: 60 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 10 mg/l
Exposure time: 16 d

Toxicity to microorganisms : IC50 (Nitrosomonas sp.): 21 mg/l
Exposure time: 24 h

Persistence and degradability

Components:

Kanamycin acid sulfate:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Phenol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 62 %
Exposure time: 10 d
Method: OECD Test Guideline 301C

Bioaccumulative potential

Components:

Phenol:

Bioaccumulation : Species: Fish
Bioconcentration factor (BCF): 17.5
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 1.47

Mobility in soil

No data available

Other adverse effects

No data available

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N.O.S.
(Kanamycin acid sulfate)

Class	:	9
Packing group	:	III
Labels	:	9
ERG Code	:	171
Marine pollutant	:	yes(Kanamycin acid sulfate)

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI	:	ACGIH - Biological Exposure Indices (BEI)
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
CA QC OEL	:	Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA	:	8-hour, time-weighted average
CA AB OEL / TWA	:	8-hour Occupational exposure limit
CA BC OEL / TWA	:	8-hour time weighted average
CA QC OEL / TWAEV	:	Time-weighted average exposure value

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International

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Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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Date format : mm/dd/yyyy

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

CA / Z8